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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,506	10/03/2005	Mao-Hsiung Yen	U 015722-1	8980

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EXAMINER	
PESELEV, ELLI	

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
04/06/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/531,506	YEN ET AL.	
	Examiner	Art Unit	
	ELLI PESELEV	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,11,12,14,18,31,39,44-46,52-54,60 and 61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *11,46,52,54 and 61* is/are allowed.

6)☒ Claim(s) *1,12,14,18,31,39,44,45,53 and 60* is/are rejected.

7)☒ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 31, 39, 44 and 45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating conditions associated with overproduction of TNF-α, does not reasonably provide enablement for liver damage, lung damage or kidney damage in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

A conclusion of scope of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the invention without undue experimentation.

(A) The breadth of the claims.

The methods claims 31, 39, 44 and 45 encompass treatment of liver damage, lung damage or kidney damage resulting from any cause and not associated with the overproduction of TNF-α or overproduction of superoxide radical such as cancer, infections, hepatitis, cirrhosis, kidney stones, tuberculosis, emphysema, etc.

(B) The level of predictability in the art.

There is no known correlation between the treatment of such unrelated diseases as cancer, infections and kidney stones and there is no known compounds that is useful for treating all such unrelated diseases.

(C) The existence of working examples.

The working example to the in vitro effect of baicalein on plasma THF-alpha, superoxide anion, nitrate and iNOS. However, there is no correlation between the levels of THF-alpha, superoxide anion, plasma nitrate and iNOS and the treatment of the diseases encompassed by the present claims. The data of record is clearly not commensurate with the full scope of the claimed invention.

(D) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Because there is no way to predict a priori if the compounds encompassed by the present claims will be useful for treating which specific disease or condition, it would take an enormous amount of experimentation to test the claimed method for its effectiveness in the treatment of liver damage, lung damage or kidney damage resulting from any number of unrelated diseases and/or conditions.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 12, 14, 18, 31, 39, 44, 45, 53 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al (WO 01/30342).

Lee et al disclose the compounds encompassed by the present claims. For example, the compound of Formula I set forth on pages 15-16 of the Lee et al reference, wherein R1 is NH2, R2 is H, R3 is H, R4 is hydroxy and R5 is H encompasses the claimed compounds. It would have been prima facie obvious to a person having ordinary skill in the art at the time of the claimed invention to select the claimed species from the genus disclosed by Lee wt al because such a person would have expected the selected species to have similar properties and activities to the genus as a whole. Further, note that Lee et al disclose the compounds to be useful in inhibiting expression of iNOS, COX-2 and to be useful in treating inflammation. Note, that the terminology such as "liver damage" encompasses inflammation of the liver. In accordance with the disclosure by Lee et al, it would have been prima facie obvious to a person having ordinary skill in the art at the time of the claimed invention to treat liver damage resulting from the inflammation.

Applicant's arguments filed January 31, 2011 have been fully considered but they are not persuasive.

Applicant contends that Lee contains no suggestion that X other than H should be present. This argument has not been found persuasive since Lee et al disclose a substituted phenyl ring.

Applicant further contends that Lee et al do not disclose the treatment of organ damage. This argument has not been found persuasive since Lee et al disclose the treatment of inflammation, and the terminology "damage" includes inflammation.

Applicant contends that Lee et al do not provide experiments to substantiate their disclosed utility. This argument has not been found persuasive since it would have been within the standard experimentation to conduct such tests.

Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory

period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev
/Elli Peselev/
Primary Examiner, Art Unit 1623